

In re Application of: Amir B. GEVA et al.
Serial No.: 10/677,176
Filed: October 2, 2003
Final Office Action Mailing Date: April 3, 2009

Examiner: Karen E. TOTH
Group Art Unit: 3735
Attorney Docket: 46434

In the Claims:

1. (Withdrawn) Method for monitoring normal/abnormal physiological events in one or more patients by the analysis of biomedical signals of each patient, comprising: for each patient,

a) aggregating one or more raw data streams, each of which representing a different type of biomedical signals of said patient, in a data storage;

b) for each type of biomedical signal, performing adaptive segmentation of said raw data streams associated with said patient, and assigning, to each segment, individual attributes being represented by attribute values;

c) determining an attribute domain, in which each segment being represented by a point that corresponds to the attribute values of said segment;

d) for each type of biomedical signal or for any combination thereof, generating a set of clusters in said attribute domain, each of which includes a combination of points determined by their relative location to other points, by assigning a set of property values to each point, each property value corresponding to the degree of association of said point with one of the clusters;

e) obtaining the probability of the order of appearance of each point, in time, according to its property value and updating the property value of each point in each cluster using said probability;

f) repeating d) to e) while in each time, varying the combination of points included in each cluster according to their most updated property value and by including points derived from adaptive segmentation of further aggregated raw data streams of said patient, thereby updating each cluster;

g) associating at least one updated cluster with a normal/abnormal physiological state of said patient by using former knowledge, regarding normal/abnormal physiological states of said patient and/or of a reference group of patients, that is represented as reference clusters in said domain; and

h) individually characterizing said patient by identifying normal/abnormal physiological states, associated with one or more updated clusters,

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and obtaining the probability of a change between normal/abnormal physiological states using said probability of the order of appearance.

2. (Withdrawn) A method according to claim 1, further comprising obtaining indications related to abnormal physiological events in the patient by displaying changes in normal physiological states of said patient as a function of time.

3. (Withdrawn) A method according to claim 1, further comprising displaying different stages of normal physiological states of the patient as a function of time.

4. (Withdrawn) A method according to claim 1, further comprising storing at least a portion of the aggregated raw data streams in an accessible data storage.

5. (Withdrawn) A method according to claim 1, further comprising retrieving the data segment that corresponds to an identified physiological disorder from the accessible data storage.

6. (Withdrawn) A method according to claim 1, wherein the types of biomedical signals are selected from EEG signals, EOG signals, EKG signals, and Respiratory signals.

7. (Withdrawn) A method according to claim 1, further comprising:

- a) Generating an individual data being a group of clusters and/or indications of normal/abnormal physiological events in each patient represented by said group;
- b) dividing each individual data into packets;
- c) transmitting the data packets of one or more patients to a remote site over a data network; and

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d) receiving said data packets in said remote site, processing the received data packets by a computerized system and displaying a representation of abnormal physiological events as a function of time and/or of changes in normal physiological states and/or different stages of normal physiological states of each patient at said remote site.

8. (Withdrawn) A method according to claim 7, further comprising:

a) transmitting a request for one or more segments of the raw data streams that correspond to abnormal physiological events from the remote site to the data storage over the data network; and

b) retrieving the requested segments from said data storage and displaying said requested segments at said remote site.

9. (Withdrawn) A method according to claim 8, further comprising:

a) transmitting instructions for a medical treatment to be given to the patient for terminating the abnormal physiological events from the remote site to a local computerized system located at the vicinity of said patient, over the data network;

b) at said remote site, receiving data packets that correspond to an individual group of data clusters that corresponds to physiological events after applying said medical treatment to said patient, processing the received data packets by the computerized system and displaying a representation of physiological events, obtained in response to said medical treatment, as a function of time and/or of changes in normal physiological states and /or different stages of normal physiological states of each patient; and

c) optionally repeating the preceding, abnormal physiological events are eliminated or substantially reduced.

10. (Withdrawn) A method according to claim 1, wherein the raw data streams are received from one or more dry electrodes attached to the skin of the

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patient and having movement detectors for identifying time periods during which segments of raw data streams are associated with patient movements.

11. (Withdrawn) A method according to claim 1, wherein the abnormal physiological events are selected from sleep apnea, cardiac arrhythmia, Ventricular Tachycardia, Ventricular Fibrillation/Flutter, and Epilepsy.

12. (Withdrawn) A method according to claim 1, wherein the raw data streams are processed by performing the following:

- a) inputting said raw data streams to a cellular device having processing means being capable of identifying irregular physiological events of the patient;
- b) generating a characteristic trace that corresponds to regular physiological events of said patient;
- c) identifying selected raw data segments that comprise irregular physiological events;
- d) transmitting said selected raw data segments over a cellular network to another computational device; and
- e) continuing processing said selected raw data segments streams and representing the processed raw data by data clusters, each of which including a set of unique properties that correspond to a different type of biomedical signal and to a different normal physiological state of said patient, by said another computational device.

13. (Withdrawn) A method according to claim 12, further comprising:

- a) representing the abnormal physiological events and/or the individual attributes of each patient by an individual group of updated data clusters;
- b) dividing each individual group into data packets;
- c) transmitting the data packets of one or more patients to a remote site over a data network; and

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d) receiving said data packets in said remote site, processing the received data packets by a computerized system and displaying a representation of abnormal physiological events as a function of time and/or of changes in normal physiological states and /or different stages of normal physiological states of each patient at said remote site.

14. (Withdrawn) A method according to claim 13, further comprising:

- a) for each patient, identifying, by another computational device, irregular physiological events;
- b) retrieving segments of raw data that corresponds to said irregular physiological events;
- c) generating a data set that comprises the retrieved segments and parameters indicating the irregularity of the irregular physiological events within said retrieved segments;
- d) transmitting said data set to a cellular device having processing means being capable of displaying said parameters and said retrieved segments, over a cellular data network; and
- e) displaying said parameters and/or said retrieved segments, on the display of said cellular device.

15. (Withdrawn) A method according to claim 1, further comprising:

- a) Generating, in real-time, alert indications representing abnormal physiological events; and
- b) Automatically transmitting said indications to a physician over a data network, for determining/providing the required medical treatment.

16. (Withdrawn) A method according to claim 1, further comprising dynamically controlling the operation of medical apparatus used for providing medical treatment to a patient being in an abnormal state in response to identified abnormal physiological events in said patient.

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17. (Withdrawn) A method according to claim 16, wherein the medical apparatus is selected from controllable drug dosage devices, controllable gas/air delivery devices, and CPAP.

18. (Withdrawn) A method according to claim 7, comprising transmitting instructions for dynamically controlling medical equipment, providing medical treatment to the patient, for terminating the abnormal physiological events from the remote site to a local computerized system located at the vicinity of said medical equipment, over the data network.

19. (Withdrawn) A method according to claim 1, wherein the analyzed biomedical signal is an ECG signal, and the analysis of said signal comprises:

- a) acquiring the patient's raw ECG signal, by utilizing a corresponding electrode;
- b) adaptive segmentation of said raw ECG signal;
- c) features extraction from said raw ECG signal;
- d) temporal and shape clustering; and
- e) medical interpretation of the clusters.

20. (Withdrawn) A method according to claim 19, wherein the adaptive segmentation comprises:

- a) generating several signals from the raw ECG signal, in each signal a different frequency content being emphasized;
- b) summation of the corresponding absolute values of said signals;
- c) filtering the resulted summation; and
- d) employing local maxima detection algorithm, for identifying the R-peaks, P-peaks and T-peaks in said filtered resulted summation, said R, P and T peaks being utilized for characterizing the corresponding heartBeats Under Test (BUTs), said P and T peaks being utilized also for segmenting heartbeats.

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21. (Withdrawn) A method according to claim 19, wherein the features extraction comprises:

- a) detecting 'R--R' time-intervals between each two consecutive R-peaks; and
- b) identifying 'P', 'Q', 'S' and 'T' points of the corresponding BUTs, by utilizing said R--R' time-intervals, said points characterize said BUT.

22. (Withdrawn) A method according to claim 19, wherein the temporal shape, clustering and medical interpretation comprise:

- a) comparing the shape of the BUT to the shape of a Universal HeartBeat (UHB) shape;
- b) whenever the resemblance of said BUT to the UHB is smaller than a first Normalized Correlation threshold value NC.sub.TH1, ignoring said BUT; otherwise
- c) storing said BUT in a storage array;
- d) whenever required, averaging the stored BUTs, for obtaining a Patient-Specific Universal HeartBeat (PSUHB);
- e) replacing said UHB by said PSUHB;
- f) for each BUT, repeating a) to e), while utilizing a second Normalized Correlation (NC) threshold value NC.sub.TH2, said second NC threshold value being larger than said first NC threshold value;
- g) whenever the resemblance of said BUT to the PSUHB is larger than the second Normalized Correlation threshold value NC.sub.TH2, storing said BUT as Normal heartbeat in a corresponding storage array;
- h) whenever required, averaging the stored Normal heartbeats, for obtaining a Patient-Specific Normal HeartBeat (PSNHB);
- i) whenever the resemblance of said BUT is smaller than the second Normalized Correlation threshold value NC.sub.TH2, carrying out a movement analysis;

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j) if a corresponding movement is detected, discarding said BUT;
 otherwise

k) comparing the shape of the BUT to the shape of a first (aberrant) Universal Pathological HeartBeat ($UPB1_{REF}$) shape and to a second (aberrant) Universal Pathological HeartBeat ($UPB2_{REF}$); l) whenever the resemblance of said BUT to said $UPB1_{REF}$, and/or to said $UPB2_{REF}$, is larger than a third Normalized Correlation threshold value NC_{TH3} , storing said BUT as Pathological heartbeat, the type of which is determined according to said $UPB1_{REF}$ or $UPB2_{REF}$, whichever yields a larger resemblance; otherwise

m) if said BUT is found to be noise, discarding said BUT;
 otherwise

n) whenever the resemblance of said BUT to said $UPB1_{REF}$, and/or to said $UPB2_{REF}$, is larger than a forth Normalized Correlation threshold value NC_{TH4} , storing said BUT as Pathological heartbeat, the type of which is determined according to said $UPB1_{REF}$ or $UPB2_{REF}$, whichever yields a larger resemblance; otherwise

o) classifying said BUT as having unknown shape;

p) whenever required, and for each type of Pathological heartbeat, averaging the stored Pathological HeartBeats, for obtaining a corresponding first Patient-Specific Universal Pathological HeartBeat ($PSUPHB1$) and a second Patient-Specific Universal Pathological HeartBeat ($PSUPHB2$); and

q) for each additional BUT, repeating l) to p), while replacing said $UPB1_{REF}$ and $UPB2_{REF}$ by said $PSUPHB1$ and $PSUPHB2$.

23. (Withdrawn) A method according to claim 22, in which the stored aberrant pathological BUTs are utilized for determining pathological sequences.

24. (Withdrawn) A method according to claim 23, wherein the pathological sequence is selected from VT, SVT, Bigeminy, Trigeminy1, Trigeminy2, Tachycardia, and Bradycardia.

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25. (Withdrawn) A method according to claim 22, wherein the BUTs are compared to the relevant shape by utilizing a corresponding Matched Filter, the parameters of which are updated whenever a new average Normal heartbeat or new Pathological heartbeat are calculated.

26. (Withdrawn) A method according to claim 22, wherein identifying the R-peaks in the acquired ECG signal is carried out by utilizing the Wavelet Transform Algorithm and several 'scales' associated with it.

27. (Withdrawn) A method according to claim 1, in which the analyzed biomedical signal is an EEG signal, and the analysis of said signal comprises:

- a) acquiring the patient's raw EEG signal;
- b) Filtering the EEG signal, EOG and EMG signals;
- c) Adaptively segmenting the resulting filtered EEG and EOG signals into Quasi-Stationary Segments (QSSs);
- d) Extracting the required features from the resulting quasi-stationary EEG and EOG segments;
- e) Preliminary classification of each EEG QSS;
- f) Whenever relevant, detecting special temporal events contained within the EEG QSS;
- g) Special events classification, by using environment characteristics;
- h) If an EOG signal exists, detection of EOG REM, by employing related algorithm; and i) Determination of sleep staging.

28. (Withdrawn) A method according to claim 27, further comprising:

- a) a 'real-time' analysis, comprising:
 - a.1) adaptive segmentation of said EEG signal, by utilizing a first and a second time-windows, the time-width and relative location being varied until a decision, regarding the optimized location of the boundaries of each EEG

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segment, is determined, based on the comparison between the statistical properties of a first EEG signal portion contained in the first time-window to the statistical properties of a second EEG signal portion contained in the second time-window;

a.2) for each identified quasi-stationary segment, associating said segment to a High Frequency Group (HFG), or to a Mixed Frequency Group (MFG) or to a Low Frequency Group (LFG), by identifying its temporal and frequency features/characteristics and by employing fuzzy logic rules, the segments associated with same group form a cluster;

a.3) whenever a segment is associated with HFG or LFG, analyzing its adjacent right-hand side and left-hand side segments, for identifying special events;

a.4) whenever said segment significantly differs from said adjacent segments, classifying said segment as special event, which does not belong to the ongoing EEG signal;

a.5) after first predetermined time-interval, averaging each one of the three related clusters;

a.6) determining the sleep stage, being associated with said time-interval, by employing a set of R&K rules on the averaged clusters and on the detected special events; and

a.7) repeating a.1) to a.6).

b) an 'off-time' analysis, during which the system converges to the inherent sleep behavior of the monitored person, said analysis being employed for a second time-interval, the duration of which being larger than the duration of said first time-interval, comprising:

b.1) initial division of the frequency groups into subgroups;

b.2) employing the Baum-Welch algorithm on the subgroups, for allowing 'learning' the monitored person by averaging the corresponding subgroups;

b.3) utilizing the averaged subgroups for refining the special event classification;

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- b.4) detecting EMG energy 'lows' using hierarchical fuzzy clustering algorithm;
- b.5) utilizing the averaged subgroups for refining sleep staging process; and
- b.6) refining arousal detection.

29. (Withdrawn) A method according to claim 1, in which the analyzed biomedical signals are Respiratory signals, and the analysis of said signal comprises:

- a) Detection and Smoothing of the Envelope (DSE) of the Chest effort signal, said effort signal, being referred to as the Master event;
- b) Peak Detection and Maximum Setting (PDMS) of the envelope signal;
- c) Identifying two consecutive global maxima points, said points defining the temporal boundaries of a corresponding segment of said envelope;
- d) Calculating the probability of a decrease of more than 20% in the magnitude of said segment;
- e) If a decrease of more than 20% is detected, for duration larger than 10 seconds, employing a Fuzzy Logic Algorithm (FLA), for evaluating the relevance of other events to said decrease, after which a decision is made regarding the probability of respiratory events; otherwise
- f) Identifying the trend of said segment, by assigning a first parabola function that mathematically approximates said segment and analyzing the characteristics of said parabola;
- g) If said trend is Downwards, assigning a second parabola function to the next detected segment;
- h) If the trend of said second parabola is Upwards, employing an algorithm for adjoining the corresponding segments, said adjoined segments form a grand segment; and
- i) Employing e) on the grand segment.

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30. (Withdrawn) A method according to claim 29, in which the evaluation process further comprises:

- a) associating a trapezoid-shaped 'Probability-Wise Window' (PWW) to a corresponding event, the shape, time width and location of said PWW, in relation to the master event, being predetermined according to clinical criteria;
- b) utilizing said PWW for assigning a probability value to the corresponding event, according to the temporal location of the event in relation to the PWW associated with it; and
- c) based on the probability values being assigned to corresponding events, calculating the probability of 'real' respiratory events detection.

31. (Withdrawn) A method according to claim 29, in which the other events are the Abdominal Effort, Limb Movement and Oxygen Saturation.

32. (Withdrawn) A method according to claim 29, in which the master event is selected from: Abdominal Effort, Limb Movement, Oxygen Saturation, and Chest Effort, to said remaining events are assigned a corresponding PWW, for allowing relating each one of said remaining events to said master event.

33. (Withdrawn) System for monitoring normal/abnormal physiological events in one or more patients by the analysis of biomedical signals of each patient, comprising:

- a) One or more sensors, attached or allocated to said patient, being capable of generating and transmitting biomedical signals;
- b) a data storage for aggregating transmitted raw data streams, each of which representing a different type of biomedical signals of said patient; and
- i) processing means, being in data communication with said sensors and/or said data storage, for performing adaptive segmentation of said raw data streams of said patient and assigning, to each segment, individual attributes being represented by attribute values determining an attribute domain, in which each

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segment being represented by a point, for generating a set of clusters in said attribute domain for each type of biomedical signal or for any combination thereof, such that each cluster includes a combination of points determined by their relative location to other points, by assigning a set of property values to each point, and such that each property value corresponds to the degree of association of said point with one of the clusters, for obtaining the probability of the order of appearance of each point, in time, according to its property value and updating the property value of each point in each cluster using said probability, for updating each cluster by iteratively varying the combination of points included in each cluster according to their most updated property value and by including points derived from adaptive segmentation of further aggregated raw data streams of said patient, for associating at least one updated cluster with a normal/abnormal physiological state of said patient by using former knowledge, regarding normal/abnormal physiological states of said patient and/or of a reference group of patients, that is represented as reference clusters in said domain and for individually characterizing said patient by identifying normal/abnormal physiological states, associated with one or more updated clusters, and obtaining the probability of a change between normal/abnormal physiological states using said probability of the order of appearance.

34. (Withdrawn) System according to claim 33, further comprising display means for displaying different stages of normal physiological states of the patient as a function of time.

35. (Withdrawn) System according to claim 33, in which the types of biomedical signals are selected from: EEG signals, EOG signals, ECG signals, and Respiratory signals;

36. (Withdrawn) System according to claim 33, further comprising:
a) Means for dividing data clusters and/or the representation of their corresponding physiological states into data packets;

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b) means for transmitting said data packets of one or more patients to a remote site over a data network;

c) means for receiving said data packets in said remote site; and

d) means for processing the received data packets and displaying a representation of abnormal physiological events as a function of time and/or of changes in normal physiological states and/or different stages of normal physiological states of each patient at said remote site.

37. (Withdrawn) System according to claim 36, further comprising:

a) means for transmitting a request for one or more segments of the raw data streams that correspond to abnormal physiological events from the remote site to the data storage over the data network; and

b) means for retrieving the requested segments from said data storage and displaying said requested segments at said remote site.

38. (Withdrawn) System according to claim 33, further comprising one or more dry electrodes attached to the skin of the patient and having movement detectors for generating and forwarding raw data streams.

39. (Withdrawn) System according to claim 13, further comprising:

a) a computational device having processing means for identifying abnormal physiological events in a patient, and being capable of generating a data set that comprises retrieved segments and parameters indicating the irregularity of the irregular physiological events within said retrieved segments and of transmitting said data set; and

b) a cellular device having processing means being capable of receiving said data set over a cellular data network, and a display for displaying said parameters and said retrieved segments.

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40. (Withdrawn) A method according to claim 1, wherein the former knowledge is capable of being continuously updated by manually modifying the characterization results.

41-42. (Canceled)

43. (Withdrawn-Currently Amended) A method for sleep diagnosis, comprising:

receiving biomedical signals from a sleeping patient over a given time period;

extracting features from the biomedical signals and grouping the features into multiple clusters;

assigning respective vectors of membership values to a plurality of intervals within the given time period, each membership value indicating a degree of association between the biomedical signals in a corresponding interval and a respective cluster among the multiple clusters; and

evaluating a condition of the patient responsively to the vectors using a state machine model which comprises machine states corresponding to physiological states of the patient.

44. (Withdrawn) The method according to claim 43, wherein evaluating the condition comprises classifying sleep stages of the patient based on the vectors.

45. (Withdrawn) The method according to claim 43, wherein receiving the biomedical signals comprises receiving electroencephalogram (EEG) signals.

46. (Withdrawn) The method according to claim 43, wherein extracting the features comprises adaptively segmenting the biomedical signals into a sequence of segments, and determining the features of each of the segments.

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47. (Withdrawn) The method according to claim 43, wherein assigning the respective vectors comprises assigning fuzzy membership values to each of the intervals.

48. (Canceled)

49. (Withdrawn) A method for sleep diagnosis, comprising:
defining a state machine model comprising machine states corresponding to physiological states of a patient, and comprising respective probabilities of transitions among the states;
receiving biomedical signals from a sleeping patient over a given time period;
segmenting the biomedical signals into a sequence of segments, and determining one or more respective features of each of the segments;
assigning respective state classifications to the segments responsively to the respective features and to the probabilities of the transitions among the states of the state machine model; and
evaluating a condition of the patient during the given time period responsively to the state classifications.

50. (Withdrawn) The method according to claim 49, wherein the physiological states comprise sleep stages, and wherein evaluating the condition comprises classifying sleep stages of the patient based on the state classifications.

51. (Withdrawn) The method according to claim 49, wherein defining the state machine model comprises defining a Hidden Markov Model (HMM).

52. (Withdrawn) The method according to claim 49, wherein assigning the respective state classifications comprises assigning respective fuzzy membership

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values to the segments, and determining the state classifications responsively to the fuzzy membership values.

53-57 (Canceled)

58. (Previously Presented) Apparatus for sleep diagnosis, comprising:

one or more sensors, which are adapted to receive biomedical signals from a sleeping patient over a given time period; and

a processor, which is adapted to extract features from the biomedical signals and to group the features into multiple clusters, to assign respective vectors of membership values to a plurality of intervals within the given time period, each membership value indicating a degree of association between the biomedical signals in a corresponding interval and a respective cluster among the multiple clusters, and to evaluate a condition of the patient responsively to the vectors,

wherein the processor is adapted to receive a state machine model comprising machine states corresponding to physiological states of the patient, and to determine the condition using the state machine model.

59. (Previously Presented) Apparatus for sleep diagnosis, comprising:

one or more sensors, which are adapted to receive biomedical signals from a sleeping patient over a given time period; and

a processor, which is adapted to receive a definition of a state machine model comprising machine states corresponding to physiological states of a patient, the model comprising respective probabilities of transitions among the states,

wherein the processor is adapted to segment the biomedical signals into a sequence of segments and determine one or more respective features of each of the segments, to assign respective state classifications to the segments responsively to the respective features and to the probabilities of the transitions among the states of the state machine model, and evaluate a condition of the patient during the given time period responsively to the state classifications.

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60. (Previously Presented) The apparatus according to claim 59, wherein the physiological states comprise sleep stages, and wherein the processor is adapted to classify sleep stages of the patient based on the state classifications.

61. (Previously Presented) The apparatus according to claim 59, wherein the state machine model comprises a Hidden Markov Model (HMM).

62. (Previously Presented) The apparatus according to claim 59, wherein the processor is adapted to assign respective fuzzy membership values to the segments, and to determine the state classifications responsively to the fuzzy membership values.

63. (New) The apparatus according to claim 58, wherein the processor is adapted to classify sleep stages of the patient based on the vectors.

64. (New) The apparatus according to claim 58, wherein the biomedical signals comprise electroencephalogram (EEG) signals.

65. (New) The apparatus according to claim 58, wherein the processor is adapted to assign fuzzy membership values to each of the intervals.